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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/656,372	09/08/2003	Bernard Massie	10890-1C	8255

25277 7590 05/03/2007

NATIONAL RESEARCH COUNCIL OF CANADA
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EXAMINER	
GROSS, CHRISTOPHER M	
ART UNIT	**PAPER NUMBER**
1639	

MAIL DATE	DELIVERY MODE
05/03/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/656,372	MASSIE ET AL.	
	Examiner	Art Unit	
	Christopher M. Gross	1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *2/9/2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-20* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Responsive to communications entered 2/9/2007. Claims 1-20 are pending.

Priority

Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120/121 as follows:

It is noted that this application appears to claim subject matter disclosed in prior Application No. 09/258,209, filed 2/25/1999. A reference to the prior application(s) must be inserted as the first sentence(s) of the specification of this application or in an application data sheet (37 CFR 1.76), if applicant intends to rely on the filing date of the prior application under 35 U.S.C. 119(e), 120, 121, or 365(c). See 37 CFR 1.78(a). For benefit claims under 35 U.S.C. 120, 121, or 365(c), the reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of all nonprovisional applications. If the application is a utility or plant application filed under 35 U.S.C. 111(a) on or after November 29, 2000, the specific reference to the prior application must be submitted during the pendency of the application and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior application. If the application is a utility or plant application which entered the national stage from an international application filed on or after November 29, 2000, after compliance with 35 U.S.C. 371, the specific reference must be submitted during the pendency of the application and within the later of four months from the date

on which the national stage commenced under 35 U.S.C. 371(b) or (f) or sixteen months from the filing date of the prior application. See 37 CFR 1.78(a)(2)(ii) and (a)(5)(ii). This time period is not extendable and a failure to submit the reference required by 35 U.S.C. 119(e) and/or 120, where applicable, within this time period is considered a waiver of any benefit of such prior application(s) under 35 U.S.C. 119(e), 120, 121 and 365(c). A benefit claim filed after the required time period may be accepted if it is accompanied by a grantable petition to accept an unintentionally delayed benefit claim under 35 U.S.C. 119(e), 120, 121 and 365(c). The petition must be accompanied by (1) the reference required by 35 U.S.C. 120 or 119(e) and 37 CFR 1.78(a)(2) or (a)(5) to the prior application (unless previously submitted), (2) a surcharge under 37 CFR 1.17(t), and (3) a statement that the entire delay between the date the claim was due under 37 CFR 1.78(a)(2) or (a)(5) and the date the claim was filed was unintentional. The Director may require additional information where there is a question whether the delay was unintentional. The petition should be addressed to: Mail Stop Petition, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

If the reference to the prior application was previously submitted within the time period set forth in 37 CFR 1.78(a), but not in the first sentence(s) of the specification or an application data sheet (ADS) as required by 37 CFR 1.78(a) (e.g., if the reference was submitted in an oath or declaration or the application transmittal letter), and the information concerning the benefit claim was recognized by the Office as shown by its inclusion on the first filing receipt, the petition under 37 CFR 1.78(a) and the surcharge under 37 CFR 1.17(t) are not required. Applicant is still required to submit the reference

in compliance with 37 CFR 1.78(a) by filing an amendment to the first sentence(s) of the specification or an ADS. See MPEP § 201.11.

Election/Restrictions

Claims 2-20 are hereby rejoined, however the following election of species has been necessitated by applicant's amendment to the claims entered 2/9/2007 therein introducing species previously not considered.

Species Election

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Each **genus** identified below is indicated in **bold.** Applicant is requested to elect one species from within *each* genus of the elected invention.

(From claim 4) **early transcriptional region:** E1,E2,E3,E4. Currently claims 1,2, 4 are generic.

Each species of "early transcription region" is directed to related products. The related products are distinct if the (1) the species as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the species do not overlap in scope, i.e., are mutually exclusive; and (3) the species as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the species as claimed have different designs in that they do not share significant sequence similarity and provide different functions in adenovirus. Furthermore, the

species as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

(From claims 6-15) **expressible exogenous DNA cassette:** applicant is required to elect one type of expressible exogenous DNA cassette, specified as to being first or second (i.e. claims 6-12 vs. 12-15), dicistronic (claim 8), and type of promoter (e.g. tetracycline-inducible). Currently claims 1,2,6-15 are generic.

Each species of "expressible exogenous DNA cassette" is directed to related products. The related products are distinct if the (1) the species as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the species do not overlap in scope, i.e., are mutually exclusive; and (3) the species as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the species as claimed have different designs in that they do not share significant sequence similarity and require a different mode of operation in that a constitutive promoter, for instance, would not require addition of tetracycline to induce expression in a adenovirus culture medium. Furthermore, the species as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

(From claims 17-18) **expressible exogenous DNA :** [directed to] antisense RNA, fragment for a protein gene, a cis-acting element regulating promoters (TATA boxes), a cis-acting element regulating enhancers, a cis-acting element regulating suppressers, a cis-acting element regulating IRES, a cis-acting element regulating polyA, a cis-acting element regulating termination sequences, a cis-acting element

regulating UTR sequences of messages that regulate the stability of mRNA, a cis-acting element regulating UTR sequences of messages that regulate the transport of mRNA. Currently claims 1,2,17,18 are generic.

Each species of "expressible exogenous DNA" is directed to related products. The related products are distinct if the (1) the species as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the species do not overlap in scope, i.e., are mutually exclusive; and (3) the species as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the species as claimed have different designs in that they do not share significant sequence similarity and require a different mode of operation in that an assay for measuring the activity of an expressed protein requires materially different steps, such as enzymatic activity, for instance; versus an assay for measuring how a cis-acting element might affect UTR sequences of messages that regulate the transport of mRNA, such as by Northern blot analysis. Furthermore, the species as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

Additionally, it is noted each of the above species can be separately classified. Consequently, the species have different issues regarding patentability and represent patentably distinct subject matter. Additionally, each of the above species are independent or distinct for the reasons given above, creating a serious burden on the examiner if restriction is not required: a prior art search of each of the species requires a

different field of search (see MPEP § 808.02). In conclusion, restriction for examination purposes as indicated is proper.

(From claims 19-20) **number of clones:** 10^3, 10^6. Currently claims 1,2,13,19-20 are generic.

Each "number of clones " is directed to related products. The related products are distinct if the (1) the species as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the species do not overlap in scope, i.e., are mutually exclusive; and (3) the species as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the species as claimed have different modes of operation in that analyzing 1000 clones may be done by hand whereas keeping track of 1000000 clones would require the use of robotics, computer databases, etc. Furthermore, the species as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after

the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher M. Gross whose telephone number is (571)272-4446. The examiner can normally be reached on M-F 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, J. Douglas Schultz can be reached on 571 272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Christopher M Gross
Examiner
Art Unit 1639

cg

J. DOUGLAS SCHULTZ, PH.D.
SUPERVISORY PATENT EXAMINER